

## **Section II (Remarks)**

No amendments to the claims have been made herewith.

### **A. Response to Rejections Under 35 U.S.C. 112, First Paragraph**

In the January 9, 2007 Office Action, claims 1-11 and 23-24 were rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to reasonably provide enablement for the proviso “when the powder contains titanium in the absence of boron and aluminum, the powder further contains silicon in an amount of at least 0.8 wt%.” In support of such rejection, the Examiner stated:

Although the specification in the table implies a proviso, the only example meeting a powder that contains titanium in the absence of boron and aluminum is comparison 5, and in this comparison, the amount of silicon is 0.8% (specific value), thus the specification only enables the claimed proviso with 0.8 wt% silicon and not at least 0.8 wt%, as claimed. In addition, the amount of silicon defined in the tables range from 0.7-1.4%, thus the amount of “at least 0.8 wt.%”, as claimed, is not enabled by the specification. Such a limited disclosure does not support the breath of the instant claims since “at least” 0.8 wt.% encompasses any and all values above 0.8 wt.% which is not clearly disclosed in the specification.

(January 9, 2007 Office Action, page 2.)

Such rejection is traversed.

#### **1. Law Regarding Enablement Commensurate In Scope With The Claims**

The Federal Circuit has repeatedly held that “the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation'.” *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Nevertheless, **not everything necessary to practice the invention need be disclosed. In fact, what is well-known is best omitted.** *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. Further the scope of enablement must only bear a “reasonable correlation” to the scope of the claims. *See, e.g., In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Whenever the Patent Office asserts that the enabling disclosure is not commensurate in scope with the scope of protection sought by the claims, **it is incumbent on the Office to establish a *prima facie* case of lack of enablement.** *In re Armbruster*, 512 F.2d 676, 185 USPQ 152 (CCPA 1975); *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). To meet the burden of proof, the **Examiner must advance acceptable reasoning inconsistent with enablement.** *In re Straheilevitz*, 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982); *In re Wright*, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); MPEP 2164.04.

The determination of the propriety of a rejection based upon the scope of a claim relative to the scope of the enablement involves two stages of inquiry. **The first is to determine how broad the claim is** with respect to the disclosure. The entire claim must be considered. **The second inquiry is to determine if one skilled in the art is enabled to make and use the entire scope of the claimed invention without undue experimentation.** MPEP 2164.08.

Claims are not rejected as broader than the enabling disclosure under 35 U.S.C. 112 for noninclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801, 806, 166 USPQ 85, 88 (CCPA 1970).

When analyzing the enabled scope of a claim, the teachings of the specification must not be ignored because claims are to be given their broadest reasonable interpretation that is consistent with the specification. “That claims are interpreted in light of the specification does not mean that everything in the specification must be read into the claims.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957, 220 USPQ 592, 597 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 835 (1984).

**Limitations and examples in the specification do not generally limit what is covered by the claims.**” MPEP 2164.08 (emphasis added). Indeed, **it is impermissible for the Patent Office to limit all claims to specific examples provided in a specification.** *In re Anderson*, 176 USPQ 331, 333 (CCPA 1973)(citing *American Anode, Inc. v. Lee-Tex Rubber Products Corp.*, 136 F.2d 581, 585, 58 USPQ 7, 11 (7th Cir. 1943) and *Smith v. Snow*, 294 U.S. 1 [at pages 11 et seq.], 24 USPQ 26, 30).

The Federal Circuit has held knowledge in the art to be sufficient to support an open-ended constituent range (i.e., “greater than 50%”) where a patent disclosure taught the mere threshold (i.e., “about 50%”) without disclosure of values exceeding that threshold.<sup>1</sup>

The **technical field and the completeness of understanding of that field dictate the scope of enablement required** to enable broad patent claims under 35 USC § 112. As noted by the predecessor court to the Federal Circuit:

[T]he first paragraph of 35 U.S.C. 112 ... requires that the scope of the claims must bear a **reasonable correlation** to the scope of enablement provided by the specification to persons of ordinary skill in the art. **In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement** in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. **In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.**

*In re Fisher*, 427 F.2d 833, 166 USPQ 18, 24 (CCPA 1970). This is consistent with multiple cases discussed in MPEP section 2164.08 (8<sup>th</sup> Ed., Rev. Oct. 2005) – the **majority of cases in which the disclosure was held to be insufficient to enable the scope of the claims involved biotechnologies and complex chemical reactions**. See, e.g., *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991)<sup>2</sup>; *Amgen v. Chugai Pharm. Co.*, 927 F.3d 1200, 18

<sup>1</sup> See *Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575-77 (Fed. Cir. 1985), affirming the trial court’s conclusion that the limitation “protein content of at least about that of solvent extracted soybean meal” was supported by the written description disclosing solvent extracted soybean meal with a protein content of about 50%. *Id.* at 1575-76. **Although open-ended and although the parent disclosure did not teach materials having greater than 50% protein content, this court said, “[t]he trial court found that the parent disclosure does support the claim language, based on the 1964 disclosure and on consideration of the knowledge possessed by those skilled in the art of extrusion of both farinaceous and proteinaceous vegetable materials in 1964.”** *Id.* at 1576. We then noted that soybean meals with protein contents above 50% were readily available commodities in 1964. We concluded that “the court did not clearly err in determining that the parent’s disclosure adequately supports the protein content of the claims in issue.” *Id.* at 1576.

<sup>2</sup> (section 112, first paragraph rejection sustained as to claims for **genetic engineering techniques for producing proteins toxic to mosquito and black fly larvae**, in view of relatively incomplete understanding of biology of cyanobacteria as of applicants’ filing date and limited disclosure by applicants of particular cyanobacterial genera operative in claimed invention)

USPQ2d 1016 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991)<sup>3</sup>; *In re Wright*, 999 F.3d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)<sup>4</sup>; *In re Goodman*, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993)<sup>5</sup>; *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 23-24 (CCPA 1970)<sup>6</sup>.

Restating a pertinent portion of the excerpt provided above, a **two-part test** for determining if an embodiment provides sufficient support for broad claims directed to **mechanical elements** is **whether:**

- (1) other embodiments may be made without difficulty; and
- (2) the performance of such other embodiments may be predicted by applying known scientific laws.

*In re Fisher*, 166 USPQ at 23-24 (CCPA 1970).

Evidence provided by applicant in support of enablement need not be conclusive but merely convincing to one skilled in the art. A declaration or affidavit is, itself, evidence that must be considered. The examiner must then weigh all the evidence before him or her, including the specification and any new evidence supplied by applicant with the evidence and/or sound scientific reasoning previously presented in the rejection and decide whether the claimed

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<sup>3</sup> (section 112, first paragraph rejection sustained as to claims directed to a **purified DNA sequence encoding polypeptides that are analogs of erythropoietin (EPO)** where only a few EPO analog genes were disclosed but claims encompassed all analogs of EPO without disclose of other genetic sequences and how to make them)

<sup>4</sup> (section 112, first paragraph rejection sustained as to claims for **live non-pathogenic vaccines and processes for making same to elicit immunoprotective activity in any animal toward any RNA virus** in view of disclosure of only a single working example directed to a uniquely tailored *in vitro* method of producing a particular recombinant virus vaccine)

<sup>5</sup> (section 112, first paragraph rejection sustained as to claims for **producing mammalian peptides in plant cells** where specification contained was limited to producing gamma-interferon in a dicot species, and the evidence supported a need for extensive experimentation to encode mammalian peptide into a monocot plant at the time of filing)

<sup>6</sup> (section 112, first paragraph rejections sustained for (1) claims covering substantially all **adrenocorticotrophic hormones (ACTH) preparations**, whether produced synthetically or by breakdown of 39 amino acid peptides, to form a polypeptide containing any number of the amino acids **for therapeutic use so long as the product exhibits the threshold activity without side effects** where the application taught only the production of 39 amino acid ACTH; and (2) claims covering products having potency (therapeutic activity) greater than 230% of the 1 International Unit standard where such potencies were not obtainable from the disclosure's teachings plus ordinary skill (with the Court specifically noting that the problem was not analogous to the context of *substantially pure* compositions due to the small or nonexistent range of possible further purification))

invention is enabled. The examiner should **never** make the determination based on personal opinion. The determination should always be based on the weight of all the evidence.” Training Materials For Examining Patent Applications With Respect To 35 U.S.C. Section 112, First Paragraph-Enablement Of Chemical/Biotechnical Applications, available at <http://www.uspto.gov/web/offices/pac/dapp/1pecba.htm>) (some emphasis in original; some emphasis added).

2. Sufficiency of Enablement of “Silicon in an Amount of At Least 0.8 wt.%”

(a) *The Present Application Does Teach Abrasive Compositions Having Silicon in Amounts Exceeding 0.8 Weight %*

The present application discloses various abrasive compositions having amounts of silicon exceeding 0.8 weight percent, including compositions having silicon in amounts of 1.3 and 1.4 weight percent, respectively (e.g., see application page 17). Upon reading the present application, a person of ordinary skill in the art would readily understand that the invention is not limited to abrasive compositions having exactly 0.8 weight percent silicon. Second Shimura Declaration, ¶ 13.

(b) *The Examiner’s Bare Conclusion or Opinion, Devoid of Reasoning or Evidence, is Insufficient to Establish a Prima Facie Case of Lack of Enablement*

It is incumbent on the Examiner to establish a *prima facie* case of lack of enablement. *In re Armbruster, supra*; *In re Marzocchi, supra*. Such *prima facie* case must be supported by “acceptable **reasoning** inconsistent with enablement.” *In re Straheilevitz, supra*; *In re Wright supra*. Evidence, not personal opinion of the examiner, is to be used to support a rejection premised on lack of enablement.<sup>7</sup>

In the January 9, 2007 Office Action at page 2, the Examiner merely states the bare conclusion that “[t]he specification does not enable any person skilled in the art to which it pertains, or with

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<sup>7</sup> Training Materials For Examining Patent Applications With Respect To 35 U.S.C. Section 112, First Paragraph-Enablement Of Chemical/Biotechnical Applications, available at <http://www.uspto.gov/web/offices/pac/dapp/1pecba.htm>)

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.” Conspicuously absent is any **reasoning** supporting such conclusion. The Examiner makes no inquiry whether, and advances no reasons why, *undue experimentation* would be required for one skilled in the art to make and use the entire scope of the claimed invention, as required to support a rejection for lack of enablement pursuant to MPEP 2164.08.

Since the Examiner has failed to advance any reasoning to support his personal opinion that enablement is lacking, and he has failed to make any inquiry whether undue experimentation would be required to practice the full scope of the claims, the rejections premised on lack of enablement are legally improper and must be withdrawn.

(c) *The Examiner Has Improperly Read the Disclosure in a Vacuum, Ignoring the Level of Knowledge and Skill in the Art*

As noted previously, not everything necessary to practice the invention need be disclosed; in fact, what is well-known is best omitted. *In re Buchner, supra*. All that is necessary is that one skilled in the art be able to practice the claimed invention, given the level of knowledge and skill in the art. E.g., *In re Fisher, supra*. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement. *Id.*

Widely varying amounts of silicon (e.g., in the form of silica (SiO<sub>2</sub>) and other chemical forms) have been well known in the art for years prior to the October 28, 2002 filing date of Japanese Patent Application No. 2002-313341 on which the present U.S. patent application is based. Second Shimura Declaration, ¶ 12.

The performance of abrasive compositions including amounts of silicon exceeding 0.8 weight percent within the scope of the claims of the present invention could be predicted by one of ordinary skill in the art at the time Applicant’s invention was made, since the effect of silicon content on specific gravity, hardness, and other pertinent characteristics of an abrasive powder could be predicted from any of scientific texts and conventional testing methods that do not require undue experimentation. Second Shimura Declaration, ¶ 14. It is clear that the Examiner here has ignored the predictable nature of the technology involved.

With the benefit of reading the present application, a person of ordinary skill in the art at the time Applicant's invention was made would be easily able to produce abrasive compositions as presently claimed – including amounts of silicon exceeding 0.8 weight percent – by merely adjusting the proportion of ingredients supplied to the tundish of the manufacturing device shown and described in the present application, and then measuring the specific gravity, particle diameter / particle size, and hardness characteristics of the resulting powder using conventional methods without requiring undue experimentation. Second Shimura Declaration, ¶ 15.

**The Federal Circuit has held knowledge in the art to be sufficient to support an open-ended constituent range (i.e., “greater than 50%”) where a patent disclosure taught the mere threshold (i.e., “about 50%”) without disclosure of values exceeding that threshold.** *Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575-77 (Fed. Cir. 1985) (as discussed hereinabove). The present case provides facts supporting enablement even more compelling than those of *Purina*. In the *Purina* case, there was no disclosure of any value greater than the 50% threshold at issue; whereas present case discloses *multiple* silicon values (e.g., 1.3 and 1.4 wt.%) exceeding the 0.8 wt.% that has been so inexplicably objectionable to the Examiner.

It is abundantly clear that the Examiner has ignored the level of knowledge and skill in the art, which knowledge is essential to the basic inquiry of what disclosure is required to enable one of ordinary skill to practice the invention of the pending claims without undue experimentation. Given the newly-submitted evidence showing that knowledge in the art extant at the time Applicant's invention was made was sufficient to support an open-ended silicon weight percent value in the pending claims, withdrawal of the claim rejections under 35 U.S.C. 112, first paragraph is warranted, and respectfully requested.

(d) *The Examiner's Lack of Enablement Rejections Are Premised on a False and Unsupportable Legal Standard That Would Require All Claim Elements to be Supported in a Single Example*

In the January 9, 2007 Office Action, the Examiner stated:

“Although multiple examples can be used to support a range (upper and lower limit), applicants are not merely claiming a range, but a proviso and it is that proviso, as a whole, that must be supported by the specification. The only example that supports the claimed proviso (in terms of components used) is comparison 5 but the amount of silicon is only 0.8%. The other examples do

not support the proviso in terms of the components, thus the examiner is unclear as to how these other examples can be used to support a silicon range if they are not defined in terms of the provisos claimed.”

Despite diligent search, the undersigned is familiar with no regulation, no MPEP provision, no case law, and no examination training guidance provision<sup>8</sup> that supports the Examiner’s position that all limitations in a proviso-containing claim must be supported in a single example or embodiment. **The Examiner is hereby challenged to provide specific authority for such position or withdraw it from the record.** It is the Examiner’s role to apply the laws and regulations to each case, not to set forth new pronouncements of law.

The premise of limiting the claims to a single example in the specification runs counter to the MPEP and case law. See, e.g., MPEP 2164.08 (“[l]imitations and examples in the specification do not generally limit what is covered by the claims”); *In re Anderson*, 176 USPQ 331, 333 (CCPA 1973)(citing *American Anode, Inc. v. Lee-Tex Rubber Products Corp.*, 136 F.2d 581, 585, 58 USPQ 7, 11 (7th Cir. 1943) and *Smith v. Snow*, 294 U.S. 1 [at pages 11 et seq.], 24 USPQ 26, 30) (“[i]t is impermissible for the Patent Office to limit all claims to specific examples provided in a specification.”)

(e) *If Sustained, the Examiner’s Lack of Enablement Rejection Would Compel a Ridiculously Narrow Claim Scope That Would Frustrate the Constitutional Purpose of Promoting Progress In the Useful Arts*

“Limiting an applicant to the preferred materials in the absence of limiting prior art would not serve the constitutional purpose of promoting the progress in the useful arts.” MPEP 2164.08(c). Likewise, limiting Applicant to the exact value of 0.8 wt.% silicon in this case confers a claim scope so narrow as to absolutely frustrate the constitutional purpose of promoting the progress in the useful arts. The present application includes several examples teaching silicon values higher than 0.8 wt.%. If the claims were limited to ONLY 0.8 wt.%, the patent would be ridiculously easy to design around since a would-be infringer could simply use any other incrementally different silicon weight percent value to distinguish the claims – even the values of 1.3 wt.% or 1.4 wt.% as specifically disclosed by Applicant.



Based on all of the foregoing, the rejections under 35 U.S.C. 112, first paragraph, are legally and factually unsupportable, and should therefore be withdrawn.

**B. Response to Insufficiency of First Declaration Under 37 CFR 1.131**

In the January 9, 2007 Office Action, the (first) declaration under 37 CFR 1.131 filed on 10/13/06 was indicated to be ineffective to show reduction to practice prior to the effective date of Bergkvist '873 reference for two reasons, namely:

- (a) the first declaration did not state where the work was done (e.g., in US/NAFTA/WTO country); and
- (b) the evidence was allegedly insufficient to establish that any and all compositions meeting the claimed criteria were reduced to practice prior to the effective filing date of the reference.

As to the latter issue, the Examiner stated that “[t]he declaration, at most, establishes that specific compositions (one with specific metal components in specific amounts) were reduced to practice prior to the reference date.” January 9, 2007 Office Action, page 4.

As detailed below, these issues have been fully addressed with the accompanying “Second Declaration of Tokihiro Shimura Under 37 C.F.R. § 1.131 in U.S. Patent Application No. 10/690,073.”

**1. Law Regarding Declarations Under 37 C.F.R. § 1.131**

“The essential thing to be shown under 37 CFR 1.131 is priority of invention and **this may be done by any satisfactory evidence of the fact.**” MPEP 715.07. The purpose of filing a [37 CFR 1.]131 affidavit is not to demonstrate prior invention, *per se*, but merely to antedate the effective date of a reference. See *In re Moore*, 58 CCPA 1340, 444 F.2d 572, 170 USPQ 260 (1971).

37 CFR 1.131(b) provides three ways in which an applicant can establish prior invention of the claimed subject matter. The showing of facts must be sufficient to show:

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<sup>8</sup> E.g., “Training Materials For Examining Patent Applications With Respect To 35 U.S.C. Section 112, First Paragraph-Enablement Of Chemical/Biotechnical Applications” (available at <http://www.uspto.gov/web/offices/pac/dapp/lpecba.htm>)

- (A) reduction to practice of the invention prior to the effective date of the reference; or
- (B) conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to a subsequent (actual) reduction to practice; or
- (C) conception of the invention prior to the effective date of the reference coupled with due diligence from prior to the reference date to the filing date of the application (constructive reduction to practice).

“[W]hen reviewing a 37 CFR 1.131 affidavit or declaration, the examiner must consider all of the evidence presented in its entirety, including the affidavits or declarations and all accompanying exhibits, records and "notes." **An accompanying exhibit need not support all claimed limitations, provided that any missing limitation is supported by the declaration itself.** *Ex parte Ovshinsky*, 10 USPQ2d 1075 (Bd. Pat. App. & Inter. 1989).

Averments made in a 37 CFR 1.131 affidavit or declaration do not require corroboration; an applicant may stand on his own affidavit or declaration if he so elects. *Ex parte Hook*, 102 USPQ 130 (Bd. App. 1953).

2. Sufficiency of Second Declaration of Tokihiro Shimura to Swear Behind Bergkvist '873

As noted previously, a Second Declaration of Tokihiro Shimura Under 37 CFR 1.131 is enclosed herewith. Such declaration states, at ¶ 10 thereof, that all of the conception and reduction to practice of the invention claimed in the present application was performed in Japan, demonstrating compliance with MPEP 715.07(c).

With regard to the silicon weight percent issue, Applicant identifies disclosure in the present application of multiple abrasive compositions having silicon in amounts greater than 0.8 weight percent, such that a person of ordinary skill in the art at the time Applicant's invention was made would readily understand that the invention is not limited to abrasive compositions having exactly 0.8 weight percent silicon. Second Shimura Declaration, ¶ 13. Additionally, Applicant attests to the fact that widely varying amounts of silicon were well known in the art for years prior to the filing date of the Japanese patent application on which the present application is

based. *Id.*, ¶ 12. Moreover, Applicant attests to the fact that the performance of abrasive compositions including amounts of silicon exceeding 0.8 weight percent within the scope of the claims of the present invention could be predicted by one of ordinary skill in the art at the time my invention was made without undue experimentation. *Id.*, ¶ 14. Accordingly, any objection to lack of demonstration of actual reduction to practice of “any and all compositions meeting the claimed criteria” (Office Action, page 4) have been overcome, since the combination of Applicant’s actual disclosure and the level of knowledge then existing in the art encompasses any amount of silicon, 0.8 weight percent or greater, that would satisfy the remaining limitations of the claims.

Furthermore, ¶ 11 of the Second Shimura Declaration states that conception of the inventive subject matter in claims 1, 23, and 24 – as evidenced by the Exhibits attached to such Declaration and including all compositions meeting the claimed criteria – was actually completed prior to the Effective Date of Bergkvist ‘873, that conception of the subject matter of the remainder of the pending claims was further completed prior to the Effective Date of Bergkvist ‘873, and that Japanese Patent Application No. 2002-313341 was filed within eight months following such conception, demonstrating reasonable diligence. The attestation to conception of the invention prior to the effective date of Bergkvist ‘873, coupled with diligence to constructive reduction to practice, provides an independent basis for establishing prior invention pursuant to 37 CFR 1.131(b).

Based on these facts, the Second Shimura Declaration is sufficient to show reduction to practice prior to the effective date of Bergkvist ‘873.

**C. Response to Rejections Under 35 U.S.C. 103(a)**

The January 9, 2007 Office Action states that claims 1-11 and 23-24 are rejected under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 6,712,873 to Bergkvist et al. (“Bergkvist ‘873”) in view of Achikita et al., for the same reasons set forth in the previous office action.

The Second Shimura Declaration enclosed herewith attests to the fact that the instant claimed invention, as recited in the pending claims, was made prior to the filing date of Bergkvist.

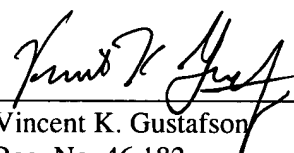
By such Declaration, Bergkvist is removed as a prior art reference.

Accordingly, withdrawal of the rejection of all pending claims under 35 U.S.C. § 103(a) is warranted, and respectfully requested.

**CONCLUSION**

Based on the foregoing, all of applicants' pending claims are in form and condition for allowance. The Examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance. If any issues require further resolution, the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to eliminate further delay in allowing the present application.

Respectfully submitted,

  
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Vincent K. Gustafson  
Reg. No. 46,182  
Attorney for Applicants

INTELLECTUAL PROPERTY/  
TECHNOLOGY LAW  
Phone: (919) 419-9350  
Fax: (919) 419-9354  
Attorney File No.: 4230-101

**Enclosure:**

**Second Declaration of Tokihiro Shimura Under 37 C.F.R. 1.131**

<p>The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284</p>
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